DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 15, 2015

Zyga Technology, Incorporated
Ms. Diane Brinza
Director of Regulatory Affairs
5600 Rowland Road, Suite 200
Minnetonka, Minnesota 55343

Re: K141549
Trade/Device Name: SImmetry® Sacroiliac Joint Fusion System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OUR
Dated: December 12, 2014
Received: December 15, 2014

Dear Ms. Brinza:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K141549

Device Name: SImmetry® Sacroiliac Joint Fusion System

Indications For Use: The SImmetry® Sacroiliac Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Prescription Use __√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

[As required by 21 CFR 807.92(c)]

Submitter / Contact Person / Date of Preparation

Submitter	Zyga Technology, Inc. 5600 Rowland Road, Suite 200 Minnetonka, MN 55343
Contact Person	Diane Brinza Director of Regulatory Affairs Ph. 952-698-9959 Fax. 952-698-9940 dbrinza@zyga.com
Date of Preparation	January 14, 2015

General Information

Trade Name	SImmetry® Sacroiliac Joint Fusion System
Common / Usual Name	Sacroiliac Joint Fixation
Classification	21 CFR Part 888.3040 Smooth or threaded metallic bone fixation fastener
Regulatory Class	Class II
Product Code	OUR
Manufacturer	Zyga Technology, Inc. 5600 Rowland Road, Suite 200 Minnetonka, MN 55343
Identification of Predicate Devices	Zyga Technology, Inc. - Slmmetry Sacroiliac Joint Fusion System (K130092) Globus Medical, Inc. - Sl-LOK Sacroiliac Joint Fixation System (K112028) Pioneer Surgical Technology, Inc. – Pioneer Cannulated Screw System (K102903) Synthes (USA) - Synthes 6.5mm Cannulated Screw (K021932)
Device Description	The SImmetry Sacroiliac Joint Fusion System consists of sterile packaged lag or fully threaded, self-tapping cannulated titanium implants designed to transfix the sacrum and ilium, providing stability for bony fusion. The surgical implants are available in various sizes to accommodate patient anatomy. Implants have major

	diameters ranging from 6.5mm - 14.5mm, in 2mm increments. Lengths in 5mm increments range from 30mm-110mm for fully threaded implants and 50mm to 110mm for partially threaded implants. All partially threaded implants and 6.5mm diameter fully threaded implants have a pre-assembled washer. Individually sterile packaged washers are available for fully threaded implants having diameters ranging from 8.5mm - 14.5mm. All devices are manufactured from Titanium Alloy (Ti-6Al-4V ELI).
Intended Use	The SImmetry Sacroiliac Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.
Summary of Non-clinical Performance Data	Tests completed for insertion torque and axial pullout strength demonstrate the subject devices are substantially equivalent with respect to mechanical performance of the K130092 predicate device. Cadaveric testing demonstrates the subject devices can be safely implanted using the SImmetry surgical technique. Additionally testing for torque to failure, mean bending yield strength and bending fatigue life provide evidence the device is capable of withstanding expected loading without failure. This performance data demonstrates that the devices included in the SImmetry Sacroiliac Joint Fusion System do not raise any new questions of safety or effectiveness.
Technological Comparison	The principle of operation of the subject devices is identical to that of the predicate devices cleared under the following submissions: • K130092 SImmetry Sacroiliac Joint Fusion System • K112028 SI-LOK Sacroiliac Joint Fixation System • K102903 Pioneer Cannulated Screw System • K021932 Synthes 6.5mm Cannulated Screw Additionally the subject devices are comprised of the same Titanium Alloy (Ti-6Al-4V ELI) and manufactured using the same manufacturing processes as the K130092 predicate device.
Conclusion	Equivalence for the SImmetry System is based on similarities in indications for use, design features, operational principles, and material composition when compared to the predicate devices cleared under the following submissions: • K130092 SImmetry Sacroiliac Joint Fusion System • K112028 SI-LOK Sacroiliac Joint Fixation System • K102903 Pioneer Cannulated Screw System • K021932 Synthes 6.5mm Cannulated Screw